

**REMARKS**

Claims 22-50 are pending in the present application. Claims 22, 33 and 42 have been amended. Claims 43-50 have been presented herewith.

**Claim Rejections-35 U.S.C. 103**

Claims 22-29, 31 and 32, ***and presumably also claims 33-42***, have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Hanss et al. reference (U.S. Patent No. 4,835,457) in view of the Graham reference (U.S. Patent No. 6,111,398). This rejection, insofar as it may pertain to the presently pending claims, is traversed for the following reasons.

The electrical impedance cell counting apparatus of claim 22 counts and characterizes particles suspended in a liquid, and includes in combination among other features a housing "with a mixing chamber and a collection chamber separated by a polymer membrane containing an orifice for passage of the particles between the mixing chamber and the collection chamber, wherein a diameter of the orifice is in a range from 10  $\mu\text{m}$  to 1,000  $\mu\text{m}$ "; electrodes "within the mixing and collection chambers configured to provide pulses by impedance determination for counting the particles that pass through the orifice"; and a volume meter "that determines a period during which a fixed volume of the liquid passes through the orifice". Applicants respectfully submit that the electrical impedance cell counting apparatus of claim 22 would not have been obvious in view of the prior art as relied upon by the Examiner for at least the following

reasons.

Applicants respectfully submit that the Hanns et al. reference does not disclose electrodes within a mixing chamber and a collection chamber that are configured to provide pulses by impedance determination for counting particles that pass through an orifice, and thus does not disclose or suggest an electrical impedance cell counting apparatus as would be necessary to meet the features of claim 22.

As emphasized in the Amendment dated June 18, 2009, the Hanss et al. reference as primarily relied upon provides **an apparatus for determining the deformability of red blood corpuscles** using a filtration method, and measuring the transit time of the corpuscles by means of electrical impedance variations. As described beginning in column 3, line 9 of the Hanss et al. reference, during the whole time corresponding to a passage of the red corpuscle through a pore, the electric resistance of the membrane is increased. The result is an electric pulse of duration substantially equal to that of the passage of the red corpuscle through the filter. This duration is called transit time of the red corpuscle. The greater the rigidity of the red corpuscle, the longer the transit time and the longer the corresponding pulse. As further described beginning in column 4, line 65 of the Hanss et al. reference, the electric impedance variations are translated into transit times, the pulses obtained are displayed as shown in Fig. 4, and histograms are obtained corresponding to the distribution of the rheological properties of the red blood corpuscles.

On page 10, lines 8-10 of the current Office Action dated August 19, 2009, the Examiner has asserted ***“that the structure taught by Hanss in view of Graham reads on the claimed invention and therefore the means in which it operates or performs a desired function is not relevant”***.

However, as emphasized above, the Hanss et al. reference measures transit times of red corpuscles through a filter to provide histograms corresponding to the distribution of the rheological properties of the red blood corpuscles. The Hanss et al. reference does not describe or suggest electrodes configured to provide pulses by impedance determination for counting the particles that pass through an orifice. Counting of cells is not mentioned in the primarily relied upon Hanss et al. reference. Contrary to the above noted assertion by the Examiner, the Hanss et al. reference as specifically relied upon by the Examiner in view of the Graham reference thus does teach or disclose the structure of claim 22.

Moreover, Applicants respectfully submit that the Examiner's apparent assertion that the “means” in which an apparatus operates or performs is irrelevant is clearly erroneous and improper. It is well settled that every feature of a claim must be considered, including functionality (see for example 35 U.S.C. 112, sixth paragraph, although these claims should not necessarily be construed under 35 U.S.C. 112, sixth paragraph). The prior art as specifically relied upon by the Examiner does not count particles passing through an orifice, and does not provide pulses for counting particles that pass through an orifice, as would be necessary to meet the features of claim 22.

Applicants therefore respectfully submit that the electrical impedance cell counting apparatus of claim 22 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection, insofar as it may pertain to claims 22-29, 31 and 32, is improper for at least these reasons.

With further regard to this rejection, Applicants respectfully submit that the Hanss et al. reference does not disclose a volume meter "that determines a period during which a fixed volume of the liquid passes through the orifice", as would be necessary to meet the still further features of claim 22.

The Examiner has alleged on page 3, lines 5-6 of the current Office Action that the Graham reference ***"describes the conduit 10 as a volumeter which measures the volume of liquid passing through"***. However, the Examiner has failed to explicitly identify such description in the Graham reference.

In particular, as described beginning in column 1, line 58 of the Graham reference with respect to Fig. 1, ***"passage of a particle through conduit 10 produces a pulsation in the current flowing through the conduit which is proportional to the volume of liquid displaced by the particle...Thus, as individual particles pass through conduit 10, sensing circuit 19 produces an electrical signal pulse having an amplitude which is characteristic of the particle volume"***(our emphasis added).

Thus, contrary to the Examiner's assertion, conduit 10 in Fig. 1 of the Graham reference provides for volume determination of particles in the liquid, and does not determine a period during which a fixed volume of liquid passes through an orifice, as

would be necessary to meet the features of claim 22. The Examiner has clearly misconstrued the Graham reference. Applicants therefore respectfully submit that the electrical impedance cell counting apparatus of claim 22 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection, insofar as it may pertain to claims 22-29, 31 and 32, is improper for at least these additional reasons.

Claim 29, as dependent upon claim 22, features that the membrane is positioned in a single-use cartridge. With respect to claim 29, the Examiner has asserted on pages 4-5 of the current Office Action that the apparatus of the Hanss et al. reference could be intended for "single use" by the user, and that claim 29 is thus obvious.

However, contrary to the Examiner's assertion, the Hanss et al. and Graham references as specifically relied upon do not disclose or suggest a cartridge, a single-use cartridge, or more particularly an electrical impedance cell counting apparatus in a single-use cartridge. In absence of such a specific teaching or suggestion within the relied upon prior art, the Examiner's assertion that the prior art as relied upon discloses or suggests the above noted features of claim 29, or that claim 29 would have somehow been obvious in view of the relied upon prior art, would appear to be based on impermissible hindsight. The term "cartridge" has not been identified in the specifically relied upon prior art. Applicants therefore respectfully submit that the electrical impedance cell counting apparatus of claim 29 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and

that this rejection, insofar as it may pertain to claim 29, is improper for at least these additional reasons.

The electrical impedance cell counting apparatus for counting and characterizing particles suspended in a liquid of claim 33 includes in combination among other features a housing "with a mixing chamber and a collection chamber separated by a polymer membrane containing an orifice for passage of the particles between the mixing chamber and the collection chamber"; and electrodes "within the mixing and collection chambers configured to provide pulses by impedance determination for counting the particles that pass through the orifice, wherein a diameter of the orifice is in a range from 10  $\mu\text{m}$  to 1,000  $\mu\text{m}$ , and wherein a diameter of the particles is not greater than 60 percent of the diameter of the orifice".

As emphasized previously, the prior art as specifically relied upon by the Examiner does not disclose or suggest an electrical impedance cell counting apparatus including electrodes configured to provide pulses by impedance determination for counting particles that pass through an orifice, as would be necessary to meet the features of claim 33. That is, the primarily relied upon Hanss et al. reference in particular discloses an apparatus that determines the deformability of red corpuscles in blood.

Moreover, the prior art as relied upon does not disclose or suggest a diameter of an orifice in a range from 10  $\mu\text{m}$  to 1,000  $\mu\text{m}$ , wherein a diameter of the particles passing through the orifice is not greater than 60 percent of the diameter of the orifice.

As emphasized in the Amendment dated June 18, 2009, and as described in column 1, lines 15-16 of the primarily relied upon Hanss et al. reference, the red corpuscles have a diameter of about 7.5  $\mu\text{m}$ . As further described in column 5, lines 13-15 of the Hanss et al. reference, the average diameter of the pores is about 5  $\mu\text{m}$ .

**This relationship is necessary in the Hanss et al. reference to deform red corpuscles passing through the pores of the filtering membrane.** The red corpuscles in the primarily relied upon Hanss et al. reference can not have a diameter not greater than 60 percent of a diameter of the pores (as would be necessary to meet the features of claim 33) and provide a measure of deformability.

Additionally, even if proper motivation existed for modifying the size of the membrane pores of the Hanss et al. reference to be larger (which motivation Applicants do not admit exists), the modified structure could not have the above noted relationship between particle diameter and pore diameter as featured in claim 33 and at the same time deform correspondingly larger cells. Applicants thus respectfully submit that claims 33-40 would not have been obvious in view of the prior art as relied upon by the Examiner for at least these reasons.

On page 6, lines 11-15 of the current Office Action, the Examiner has asserted the following with respect to claim 33: ***“the limitation of “wherein a diameter of the***

***particles is not greater than 60 percent of the diameter of the orifice" is deemed to be a limitation of the particles and not of the apparatus itself".***

Applicants respectfully submit that this position as taken by the Examiner with respect to claim 33 is clearly erroneous and improper. Claim 33 as noted above relates the diameter of the orifice to the diameter of the particles which pass through the orifice. That is, claim 33 merely states that the diameter of the orifice is in a range from 10  $\mu\text{m}$  to 1,000  $\mu\text{m}$  (which is clearly descriptive of structure), and that the diameter of the particle for a corresponding diameter of the orifice within the range is not greater than 60 percent of that corresponding diameter of the orifice. This feature taken as a whole is not merely a limitation of the particle as asserted by the Examiner, but touches on the structure of the apparatus and how the size of the orifice relates to the size of the particle. The Examiner's disregard of the above noted features is clearly improper. As emphasized previously above, the prior art as relied upon does not disclose or suggest such a relationship between orifice diameter and particle diameter. Applicants thus respectfully submit that claims 33-40 would not have been obvious in view of the prior art as relied upon by the Examiner for at least these additional reasons.

Applicants also respectfully submit that dependent claim 37, which features that the membrane is positioned in a single-use cartridge, would not have been obvious in view of the prior art as relied upon by the Examiner at least for somewhat similar reasons as set forth above with respect to claim 29, in addition to the reasons as set forth above with respect to claim 33.



Regarding dependent claim 40, as emphasized previously above, conduit 10 in Fig. 1 of the Graham reference provides for **volume determination of particles** in the liquid, and does not determine a period during which a fixed volume of liquid passes through an orifice. Accordingly, Applicants respectfully submit that claim 40 would not have been obvious in view of the relied upon prior art for at least the above reasons, in addition to the reasons as set forth with respect to claim 33.

Claim 41 is a single-use disposable electrical impedance cell counting cartridge for counting and characterizing particles suspended in a liquid, and includes in combination among other features a mixing chamber and a collection chamber separated by a polymer membrane containing an orifice.

Somewhat similarly as emphasized previously above, the Hanss et al. and Graham references as specifically relied upon do not disclose or suggest a cartridge, a single-use cartridge, or more particularly a single-use disposable electrical impedance cell counting cartridge. In absence of such a specific teaching or suggestion within the relied upon prior art, the Examiner's assertion that the prior art as relied upon discloses or suggests a single-use disposable electrical impedance cell counting cartridge of claim 41, or that claim 41 would have somehow been obvious in view of the relied upon prior art, would appear to be based on impermissible hindsight. The term "cartridge" has not been identified in the specifically relied upon prior art. There is no recognition in the relied upon prior art of any advantages realized from a single-use disposable electrical impedance cell counting cartridge. This should be self evident because the

relied upon prior art does not disclose a cartridge. Applicants therefore respectfully submit that the single-use disposable electrical impedance cell counting cartridge of claim 41 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection of claims 41 and 42 is improper for at least these reasons.

With further regard to this rejection, conduit 10 in Fig. 1 of the Graham reference provides for **volume determination of particles** in the liquid, and does not determine a period during which a fixed volume of liquid passes through an orifice, as would be necessary to meet the features of claim 42. The Examiner has clearly misconstrued the Graham reference. The Examiner has failed to specifically identify how the prior art can be interpreted to disclose determination of a period during which a fixed volume of liquid passes through an orifice. Applicants therefore respectfully submit that claim 42 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection of claim 42 is improper for at least these reasons, in addition to the reasons as set forth above with respect to claim 41.

Claim 30 has been rejected under 35 U.S.C. 103(a) as being unpatentable over the Hanss et al. and Graham references, in further view of the Berndtsson et al. reference (WO99/01742). Applicants respectfully submit that the secondary Berndtsson et al. reference a specifically relied upon does not overcome the above noted deficiencies of the primarily relied upon prior art as emphasized above with respect to claim 22, and that this rejection is improper for at least these reasons.

**Claims 43-50**

Dependent claims 43 and 46 each respectively feature a volume metering chamber having an entrance connected to the collection chamber, and having a detector that detects liquid at the entrance and at an exit of the volume metering chamber. Dependent claim 49 also features a volume metering chamber having an entrance connected to the collection chamber and having an exit, the entrance and the exit are configured to detect presence of the liquid.

The Examiner has interpreted conduit 10 in the Graham reference as the volume meter of the claims. However, as noted above, conduit 10 in Fig. 1 of the Graham reference provides for **volume determination of particles** in the liquid, and does not determine a period during which a fixed volume of liquid passes through an orifice, as would be necessary to meet the features of these dependent claims. Consequently, the Graham reference also clearly fails to disclose or suggest a volume meter including a volume metering chamber having a detector that detects liquid at an entrance and an exit of the volume metering chamber. Accordingly, Applicants respectfully submit that claims 43, 46 and 49 distinguish over and would not have been obvious in view of the prior art as specifically relied upon by the Examiner for at least these reasons.

**Conclusion**

The Examiner is respectfully requested to reconsider and withdraw the corresponding rejections, and to pass the claims of the present application to issue, for

at least the above reasons.

In the event that there are any outstanding matters remaining in the present application, please contact Andrew J. Telesz, Jr. (Reg. No. 33,581) at (571) 283-0720 in the Washington, D.C. area, to discuss these matters.

Pursuant to the provisions of 37 C.F.R. 1.17 and 1.136(a), the Applicants hereby petition for an extension of three (3) months to February 19, 2010 for the period in which to file a response to the outstanding Office Action. The required fee of \$1110.00 should be charged to Deposit Account No. 50-0238.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment for any additional fees that may be required, or credit any overpayment, to Deposit Account No. 50-0238.

Respectfully submitted,

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